

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO**

Pérez-Maceira, et al.,
Plaintiffs,

v.

Customed, Inc., et al.,
Defendants.

Civil No. 23-1445 (CVR)

OMNIBUS REPORT AND RECOMMENDATION

Pending before the Court are motions to dismiss the Amended Complaint filed by Customed, Inc. (“Customed”), Medtronic PR, Inc. (“Medtronic”), Edward LifeSciences Technology SARL (“Edward LifeSciences”), and Steri-Tech, Inc., (“Steri-Tech”) (collectively, the “Sterilizer Defendants”), Mays Chemical Company of Puerto Rico, Inc. (“Mays”) and Balchem Corp. (“Balchem”). Docket Nos. 75, 76, 78, 79. Plaintiffs opposed at Docket No. 83. Defendants replied. Docket Nos. 84, 87, 90, 91. The matters were referred to the undersigned for a Report and Recommendation. Docket No. 92. For the reasons discussed below, I recommend that the Motions to Dismiss at Docket Nos. 76 and 79 be **GRANTED in part and DENIED in part**, and the Motions to Dismiss at Docket Nos. 75 and 78 be **GRANTED**.

I. Legal Standard

A defendant may move to dismiss an action for failure to state a claim upon which relief may be granted pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. Fed. R. Civ. P. 12(b)(6). To survive a motion to dismiss, a complaint must establish “a plausible entitlement to relief.” Bell Atl. Corp. v. Twombly, 550 U.S. 544, 559 (2007); Rodríguez–Ortiz v. Margo Caribe, Inc., 490 F.3d 92, 95 (1st Cir. 2007); Fed. R. Civ. P. 12 (b)(6). A claim is plausible when the facts alleged allow for “a reasonable inference that the defendant is liable for the misconduct alleged.” Ashcroft v. Iqbal, 556 U.S. 662, 663-64 (2009). The factual allegations must be sufficient “to raise

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a right to relief above the speculative level.” Twombly, 550 U.S. at 555. In considering a motion to dismiss, the Court must accept the well-pleaded factual allegations in the complaint as true and resolve all inferences in favor of the plaintiffs. Mississippi Pub. Employees' Ret. Sys. v. Bos. Sci. Corp., 523 F.3d 75, 85 (1st Cir. 2008); ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008). The plaintiff “bears the burden of stating factual allegations regarding each element necessary to sustain recovery under some actionable theory.” Díaz-O’Neill v. Mun. of Carolina, 2024 WL 3495897, at * 1 (D.P.R. July 22, 2024). The plausibility standard assumes “pleaded facts to be true and read in a plaintiff’s favor.” Sepúlveda–Villarini v. Dep’t of Educ. of P.R., 628 F.3d 25, 30 (1st Cir. 2010). But courts need not entertain complaints supported only by “bald assertions, unsupportable conclusions, periphrastic circumlocutions, and the like.” Díaz-O’Neill, 2024 WL 3495897, at *1 (cleaned up). Unadorned factual statements and pure speculation are insufficient. Id.

II. Discussion

On August 29, 2023, Jeanette Pérez-Maceira, José Luis Mateo-Pérez, and Lilliam Ortiz filed the original complaint, asserting individual and class claims for personal injuries. Docket No. 1. They alleged to have unknowingly inhaled and been subjected to ethylene oxide (“EtO”) emissions for decades, causing them illnesses. EtO is used in the sterilization of medical instruments. The use of EtO in Puerto Rico was approved by the Department of Natural and Environmental Resources and the Environmental Protection Agency. See Docket No. 76 at pp. 3-6. Both agencies have issued permissions to operate to each of the Sterilizer Defendants. Id. On February 9, 2024, the complaint was amended to join seventeen (17) plaintiffs. Docket No. 65. After Defendants pointed to several deficiencies in the amended complaint, the Court granted leave so that plaintiffs could again amend the complaint. Plaintiffs filed the operative complaint on February 29, 2024 (“Amended Complaint”). Docket No. 74. Only ten plaintiffs are included in the Amended Complaint at Docket No. 74: Jeanette Pérez-Maceira, José Luis Mateo-Pérez, Lilliam M. Ortiz, Danisha M. Ortiz-Santiago, Yamel Santiago-Rivera, Elba Meléndez-Figueroa, Lianibel Colón-Sánchez, Iris M. Rivera-Vargas, Idalia Vargas-Gratacós, and Juana Castro-Moreno. In the Amended Complaint, Plaintiffs, individually and on behalf of the proposed class (all individuals who have resided, worked, or attended daycare and/or school within a four-mile radius of the facilities of the Sterilizer Defendants beginning on the date of initial emissions of EtO by each of

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the Sterilizer Defendants), allege that the Sterilizer Defendants, along with Balchem and Mays,¹ have emitted “substantial quantities of EtO into the air, causing those who live, work, pray, and attend school near their facilities to inhale EtO on a routine basis.” *Id.*

The Amended Complaint alleges that Defendants have released “unsafe and hazardous levels” of EtO into the atmosphere, “poisoning the air in four Puerto Rican communities.” *Id.* at pp. 3, 8. According to Plaintiffs, Defendants (1) have released EtO, (2) contaminated the surrounding neighborhoods with EtO emissions, and (3) caused harm and a significantly increased risk of disease to Plaintiffs. *Id.* at p. 17. Each plaintiff claiming personal injury was diagnosed with a health condition allegedly caused by Defendants’ contamination. These include asthma, breast cancer, thyroid cancer, spina bifida, arthritis, maxillary sinus cancer, uterine cancer, high blood pressure, and melanoma. Docket No. 74 at pp. 18-19. The diagnosis of each plaintiff was made more than a year before the filing of the instant action. *Id.* Plaintiffs assert eleven (11) causes of actions against Defendants: negligence (count one), gross negligence (count two), public nuisance pursuant to P.R. Laws Ann. tit. 32 § 2761 (count three), strict liability-design defect pursuant to P.R. Laws Ann. tit. 31 § 10807 (count four), strict liability-design defect pursuant to P.R. Laws Ann. tit. 31 § 5141 (count five), strict liability-failure to warn pursuant to P.R. Laws Ann. tit. 31 § 108006 (count six), strict liability-failure to warn pursuant to P.R. Laws Ann. tit. 31 § 5141 (count seven), negligent design defect (count eight), gross negligent design defect (count nine), private nuisance pursuant to P.R. Laws Ann. tit. 32 § 2761 (count ten), and unjust enrichment (count eleven). They seek declaratory relief, compensatory and punitive damages, and the creation of a fund for a medical monitoring program. *Id.* at pp. 23-38.

1. Streamlining the Claims Against Defendants

Plaintiffs make allegations against Defendants collectively and have thus not alerted Defendants of specific actions attributed to each one. Ordinarily, “a ‘complaint should at least set forth minimal facts as to who did what to whom, when, where, and why – although why, when why means the actor’s state of mind, can be averred generally.’” *Betancourt v. Kimco PR Mgmt.*

¹ Although Plaintiffs claim that Balchem is a manufacturer of EtO, Balchem argues that “it has never manufactured EtO. Rather, Balchem repackages EtO and distributes it as a sterilant to third parties[.]” Docket Nos. 75 at p. 3; 83 at p. 29. Similarly, while Plaintiffs claim that Mays is a distributor (Docket No. 74 at p. 7), Mays argues that it merely provides “freight services” to Balchem. Docket No. 78. Whether Balchem is a manufacturer of EtO and Mays is a distributor of EtO is of no consequence at this juncture. There is no dispute that Balchem and Mays do not operate a sterilizing facility in Puerto Rico.

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Corp., 2023 WL 6393065, at *5 (D.P.R. Sept. 30, 2023) (quoting Figueroa-Collazo v. Ferrovia Construcción PR, LLC, 2021 WL 4482268, at *9 (D.P.R. Sept. 30, 2021)). Nonetheless, group pleadings are not automatically excluded under Rule 8(a) of the Federal Rules of Civil Procedure. At the motion to dismiss stage, a complaint generally will only be dismissed where it is “‘entirely implausible’ [] for the grouped defendants to have acted as alleged.” Id. Adhering to this liberal standard, I proceed to examine the sufficiency of the pleadings for each cause of action asserted by Plaintiffs.

Notwithstanding the foregoing, Plaintiffs’ Amended Complaint at Docket No. 74 hinges on the alleged proximity of each individual plaintiff to EtO emissions: the affected plaintiffs are those who live, work, pray, and attend school in the area surrounding the facilities of the Sterilizer Defendants (id. at ¶¶ 3-4) and the affected communities are those surrounding the sterilization facilities (id. at ¶ 66). Defendants urge the Court to dismiss the claims that cannot be attributed to each Defendant. Plaintiffs do not address this request. And indeed, the proposed class is defined and limited to those who “have resided, worked[,], or attended daycare and/or school **within a four-mile radius**” of the sterilizing facilities. Id. at ¶ 96 (emphasis added). It follows that each plaintiff’s claims are actionable only against the sterilization facility within four miles of his or her respective home, school, or work. For this reason and pursuant to the allegations in the Amended Complaint, the claims of Jeanette Pérez-Maceira, José Mateo-Pérez, Lilliam Ortiz, Danisha Ortiz-Santiago, Yamel Santiago-Rivera, Elba Meléndez-Figueroa, Lianibel Colón-Sánchez against Medtronic, Customed, and Edwards LifeSciences should be dismissed because these plaintiffs reside, or have resided, in Salinas, within four miles of Steri-Tech. The claims of Idalia Vargas Gratacós against Steri-Tech, Customed, and Edwards LifeSciences should be dismissed because she resides, or has resided, in Villalba, within four miles of Medtronic. The claims of Juana Castro Moreno claims against Medtronic, Steri-Tech, and Edwards LifeSciences should be dismissed because she resides, or has resided, in Fajardo, within four miles of Customed. And the claims of Iris Rivera-Vargas against Steri-Tech, Medtronic, and Customed should be dismissed because she worked in Añasco from the year 2006 to 2008, within four miles of Edward LifeSciences. The remaining claims are: (1) those of Jeanette Pérez-Maceira, José Mateo-Pérez, Lilliam Ortiz, Danisha Ortiz-Santiago, Yamel Santiago-Rivera, Elba Meléndez-Figueroa, and Lianibel Colón-Sánchez against Steri-Tech, Balchem, and Mays, (2) those of Idalia Vargas Gratacós against Medtronic, Balchem, and Mays, (3) those of Juana Castro Moreno against Customed, Balchem,

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and Mays, and (4) those of Iris Rivera-Vargas against Edward LifeSciences, Balchem, and Mays. I examine the sufficiency of the pleadings as to those claims.

2. Statute of Limitations

Defendants argue that Plaintiffs’ claims are barred by the one-year statute of limitations for tort claims because they failed to file suit within a year of their injuries. Docket Nos. 75, 76, 78, 79. Sterilizer Defendants argue that Plaintiffs should have known of their injuries more than a year before filing the lawsuit because, as acknowledged in the Amended Complaint, there have been plenty of articles and reports about the harm of EtO exposure. In the Amended Complaint, Plaintiffs refer to a 2022 Environmental Protection Agency (“EPA”) announcement that placed Sterilizer Defendants’ facilities in a “red flag” list of sites with higher risk of EtO exposure to Puerto Rico citizens, to a report by the Union of Concerned Scientists issued on February 7, 2023 (the “UCS Report”), regarding EtO exposure in Puerto Rico, and to a 2018 EPA report based on a national air toxic assessment made in 2014 (“2018 NATA”). Docket No. 76 at p. 28. See also Docket No. 74 at ¶¶ 7-8, 47, 90-91. Sterilizer Defendants argue that EPA conducted meetings alerting communities about potential EtO exposure. The meetings took place in Fajardo on January 26, 2023 (Customed), in Villalba on January 24, 2023 (Medtronic), and in Añasco on June 23, 2021 (Edward LifeSciences).² Docket No. 76 at p. 29. Plaintiffs have not pointed to the exact date when they became aware of the causal link between Defendants’ actions and their injuries. Plaintiffs generally rely on the notion that the average citizen cannot comprehend technical issues, such as the effect of EtO emissions. See Docket No. 83 at p. 18 (“Expecting an average plaintiff to sufficiently investigate such a complex issue is unreasonable;” “Defendants fail to provide the means via which a reasonable and prudent person would learn about this EtO exposure.”). And Plaintiffs sustain that the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (“CERCLA”), 42 U.S.C. § 9601 et seq., the American Pipe tolling doctrine, and the continuous violation doctrine apply.

Sterilizer Defendants move the Court to take judicial notice of the UCS Report and the EPA meetings in Fajardo on January 26, 2023, in Villalba on January 24, 2023, and in Añasco on June 23, 2021. These are offered to establish when the relevant information became publicly available to establish a date certain when Plaintiff knew or should have known of the cause of their alleged injuries. Under Rule 201(b) of the Federal Rules of Evidence, a district court can take

² Steri-Tech did not argue that EPA meetings took place in Salinas during the relevant time.

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judicial notice of a fact that is not in dispute when it: “(1) is generally known within the trial court’s territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.” Fed. R. Evid. 201(b). Plaintiffs have not opposed the request for judicial notice, nor have they disputed the date of the UCS Report or of the EPA meetings. I take judicial notice of the fact that the UCS Report was published and made available online on February 7, 2023, and that EPA meetings took place in Fajardo on January 26, 2023, in Villalba on January 24, 2023, and in Añasco on June 23, 2021.

A federal court sitting in diversity must apply state substantive law. Suero-Algarín v. CMT Hosp. HIMA San Pablo Caguas, 957 F.3d 30, 39 (1st Cir. 2020). For diversity tort actions such as this one, Puerto Rico substantive law controls. The claims before the Court arise from Puerto Rico’s general tort statute.³ Article 1802 of the Puerto Rico Civil Code provided that “[a] person who by an act or omission causes damage to another through fault or negligence shall be obliged to repair the damage done.” P.R. Laws Ann. tit. 31 § 5141. A one-year statute of limitations applies to claims under Article 1802 or Article 1536. That period ordinarily begins to accrue “at the time that the aggrieved party knows (or should have known) of both his [or her] injury and the identity of the party who caused it.” González-Figueroa v. J.C. Penney Puerto Rico, Inc., 568 F.3d 313, 318 (1st Cir. 2009). See P.R. Laws Ann. tit. 31 § 5298 (the statute of limitations for filing a tort claim under Article 1802 commences when “the aggrieved person had knowledge thereof.”). A plaintiff has knowledge of the injury when he or she has notice of (1) the injury and (2) the person who caused it. Rodríguez-Suris v. Montesinos, 123 F.3d 10, 13 (1st Cir. 1997). A person may have actual knowledge or may be otherwise deemed to be on notice. “Actual knowledge” occurs when a plaintiff is “aware of all the necessary facts and the existence of a likelihood of a legal cause of action.” Alejandro-Ortiz v. Puerto Rico Elec. Power Auth., 756 F.3d 23, 27 (1st Cir. 2014) (quoting Rodríguez-Suris, 123 F.3d at 14). A plaintiff “is deemed to be on notice of [his or] her cause of action if [he or] she is aware of certain facts that, with the exercise of due diligence, should lead [him or] her to acquire actual knowledge of [his or] her cause of action.” Rivera-Carrasquillo v.

³ Although a new Civil Code was adopted in 2020, the Puerto Rico general tort statute did not suffer substantial changes. See González-Ortiz v. Puerto Rico Aqueduct and Sewer Auth., 2024 WL 3759659, at *10-11 (D.P.R. Aug. 12, 2024); QBE Seguros v. Morales-Vázquez, 2023 WL 3766078, at *3 (D.P.R. June 1, 2023). Because the events giving rise to this action allegedly took place before and after the 2020 Civil Code came into effect, I refer to both. See Orellano-Laureano v. Inst. Médico del Norte, Inc., 2023 WL 4532418, at *6 n.5 (D.P.R. July 13, 2023); Candelaria-Fontanez v. Federal Bureau of Prisons, 2023 WL 2895150, at *3 (D.P.R. April 11, 2023); Wiscovitch v. Cruz, 2022 WL 1272153, at n.15 (D.P.R. Jan 28, 2022).

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Centro Ecuestre Madrigal, Inc., 812 F.3d 213, 216 (1st Cir. 2016) (cleaned up). If a plaintiff asserts a cause of action more than a year after the injury, “[he or] she bears the burden of proving that [he or] she lacked the requisite ‘knowledge’ at the relevant times” and that the statute of limitations period of one year has been tolled. Alejandro-Ortiz, 756 F.3d at 27 (quoting Hodge v. Parke Davis & Co., 833 F.2d 6, 7 (1st Cir. 1987)).

Defendants posit that Plaintiffs’ allegations and causes of action sounding in tort were filed after the one-year limitations period elapsed and that they failed to demonstrate lack of knowledge during the statutory period to allow them to file suit more than a year after being diagnosed with their respective health conditions. Plaintiffs counter that CERCLA preempts Puerto Rico’s tort statute of limitations,⁴ the American Pipe tolling doctrine applies to plaintiffs who joined the suit after the original complaint was filed on August 29, 2023, and that the continuous tort doctrine applies due to the ongoing emission of EtO by the Sterilizer Defendants. Docket No. 83. Overall, Plaintiffs sustain that they “should not be required – as a threshold matter – to have played Sherlock Holmes and Dr. Watson, delving into complex investigations to discover their own claims” given

⁴ Plaintiffs’ arguments that CERCLA preempts Puerto Rico’s statute of limitations can be easily discarded. Section 9658 of the CERCLA provides:

Actions under State law for damages from exposure to hazardous substances

(a) State statutes of limitations for hazardous substance cases

(1) Exception to State statutes

In the case of any action brought under State law for personal injury [...] which [is] caused or contributed to by exposure to any hazardous substance, or pollutant or contaminant, released into the environment from a facility, if the applicable limitations period for such action (as specified in the State statute of limitations or under common law) provides a commencement date which is earlier than the federally required commencement date, such period shall commence at the federally required commencement date in lieu of the date specified in such State statute.

42 U.S.C. § 9658. The effect of this provision is “to ensure that if a state statute of limitations provides a commencement date for claims of personal injury resulting from release of contaminants that is earlier than the commencement date defined in § 9658, then plaintiffs benefit from the more generous commencement date.” O’Connor v. Boeing North America, Inc., 311 F.3d 1139, 1146 (9th Cir. 2002). But naturally, if the commencement date under state law is later than under federal law, or they are the same, the state statute of limitations applies. Id. Such is the case here. Under both CERCLA and Puerto Rico law, the discovery rule provides that the one-year statute of limitations does not begin to accrue until a plaintiff discovers, or reasonably could have discovered, his or her claim. Because both CERCLA and Puerto Rico standards are the same, the Puerto Rico one-year statute of limitations applies and CERCLA is unhelpful for Plaintiffs. See id.

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that the harm caused by exposure to EtO “is not nearly as widely known or generally understood.” Docket No. 83 at pp. 18-19.

These few things are clear: the alleged injuries occurred one year prior to the filing of this suit, Plaintiffs acknowledge that they learned of the identity of the alleged tortfeasors in 2022, and the suit was first filed on August 29, 2023. Also, Defendants seem to concede that the original plaintiffs— Jeanette Pérez-Maceira, José Luis Mateo-Pérez, and Lilliam Ortiz— filed the complaint within a year of the 2022 EPA announcement of the facilities causing higher risk of EO exposure to Puerto Rico citizens. Plaintiffs allege that it was at that time, in the year 2022, when they first became aware of the entities responsible for their alleged injuries, triggering the commencement of the limitations period. Docket No. 74 at p. 20. Plaintiffs further argue that EtO exposure is a “complex issue,” not easy to investigate, and that Defendants did not provide any warnings against EtO exposure. Docket No. 83 at p. 18. Customed, Medtronic, and Edward LifeSciences claim that the EPA held meetings in the municipalities where they operate their facilities informing citizens about EtO exposure. But Jeanette Pérez-Maceira, José Luis Mateo-Pérez, and Lilliam Ortiz’s claims are against Steri-Tech and Steri-Tech has not argued that the EPA held similar meetings in Salinas. Further, none of the Sterilizer Defendants have argued, much less pointed to evidence, that could establish that any of the plaintiffs had knowledge of such meetings, attended the meetings, or were provided information disseminated during those meetings. Although in the Amended Complaint Plaintiffs refer to public reports on EtO issued years prior to the filing of the instant action, there is no evidence that Plaintiffs had access to any such reports at the time of publication. Accepting all well pleaded factual allegations as true and drawing all reasonable inferences in favor of the pleadings— as we should at this juncture— the original plaintiffs (i.e., Jeanette Pérez-Maceira, José Luis Mateo-Pérez, and Lilliam Ortiz) have sufficiently pled that it was not until 2022 that they learned of the identity of the entity responsible for their injuries— Steri-Tech. See Rivera-Carrasquillo, 812 F.3d at 216 (The statute of limitations “begins running at the time a reasonably diligent person would discover sufficient facts to allow her to realize that she had been injured and to identify the party responsible for that injury.” And the date on which a plaintiff would have learned enough information to file an action presents a question of fact that should be submitted to the jury). At this juncture, it is reasonable to conclude

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that Jeanette Pérez-Maceira, José Luis Mateo-Pérez, and Lilliam Ortiz’s claims against Steri-Tech, Balchem, and Mays are timely.⁵

I consider the timeliness of the claims brought by the plaintiffs who were added to the instant action after the filing of the original complaint: Danisha Ortiz-Santiago, Yamel Santiago-Rivera, Elba Meléndez-Figueroa, Lianibel Colón-Sánchez, Iris Rivera-Vargas, Idalia Vargas-Gratacós, and Juana Castro-Moreno (collectively, the “New Plaintiffs”). Docket Nos. 65, 74. Defendants contend that New Plaintiffs’ claims are untimely because they did not bring their claims within a year of their respective diagnosis. Additionally, that these New Plaintiffs have failed to allege reasonable diligence to toll the one-year limitations period. Relying on the American Pipe tolling doctrine, the New Plaintiffs counter that they “were putative members of the class before becoming named members upon amendment, and thus had their statutes of limitations tolled.” Docket No. 83 at pp. 19-21. Edwards LifeSciences, Medtronic, and Customed reply that Iris Rivera-Vargas, Idalia Vargas-Gratacós, and Juana Castro-Moreno cannot seek refuge under the American Pipe doctrine because, even though Edwards LifeSciences, Medtronic, and Customed were named defendants in the original complaint, the allegations in that complaint were solely against Steri-Tech— none of the original plaintiffs alleged any EtO exposure from emissions by Edwards LifeSciences, Medtronic, and Customed— as the original plaintiffs lived near Steri-Tech’s facilities in Salinas. Steri-Tech joined Edwards LifeSciences, Medtronic, and Customed’s argument against the application of the American Pipe tolling doctrine.

In American Pipe, the U.S. Supreme Court held that “the commencement of a class action suspends the applicable statute of limitations as to all asserted members of the class who would have been parties had the suit been permitted to continue as a class action.” Id. at 554. In other words, the filing of a class action tolls the statute of limitations “as to all asserted members of the class” until class certification is denied. Crown, Cork & Seal Co., Inc. v. Parker, 462 U.S. 345, 350 (1983) (quoting American Pipe, 414 U.S. at 554)). American Pipe is consistent with the

⁵ Because Plaintiffs bear the burden of proving that knowledge of the injury and the identity of the entity responsible was not acquired until less than one year prior to the date in which the complaint was filed, the Court could revisit this issue if presented by Defendants after conclusion of discovery under Rule 56 of the Federal Rules of Civil Procedure. See María v. Colón, 2024 WL 421381 (D.P.R. Sept. 16, 2024); O’Connor v. Boeing North America, Inc., 311 F.3d 1139, 1156 (9th Cir. 2002) (reversing the grant of summary judgment because it was for the jury to determine whether plaintiffs had discovered all the essential facts constituting their cause of action prior to a report released in 1997, which plaintiffs claimed put them on notice that defendant’s facilities were the likely cause of plaintiffs’ illnesses).

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purpose of a statute of limitation as “[l]imitation periods are intended to put defendants on notice of adverse claims and to prevent plaintiffs from sleeping on their rights.” Id. at 532. In class actions, the complaint notifies defendants “not only of the substantive claims being brought against them, but also of the number and generic identities of the potential plaintiffs who may participate in the judgment.” American Pipe, 414 U.S. at 555. The defendant will thus be made aware of the need to “preserve evidence and witnesses respecting the claims of all the members of the class,” which prevents “unfair surprises.” Crown, Cork & Seal Co., Inc., 462 U.S. at 353.

Plaintiffs urge the Court to find that the American Pipe tolling doctrine applies here because New Plaintiffs are putative class members, and Puerto Rico courts have adopted the doctrine. Docket No. 83 at p. 20. See Rivera Castillo v. Mun. de San Juan, 130 P.R. Dec. 683, 1992 WL 755604 (1992). I first consider whether the American Pipe doctrine applies to the subset of New Plaintiffs that assert claims against Steri-Tech, Balchem, and Mays: Danisha Ortiz-Santiago, Yamel Santiago-Rivera, Elba Meléndez-Figueroa, and Lianibel Colón-Sánchez. The original plaintiffs filed the present action on August 29, 2023. Nearly six months later, the original plaintiffs amended the complaint to include Danisha Ortiz-Santiago, Yamel Santiago-Rivera, Elba Meléndez-Figueroa, and Lianibel Colón-Sánchez. Just like the plaintiffs in the original complaint, these New Plaintiffs allege to have been put on notice of the entity responsible for their alleged injuries in 2022, when the EPA announced a list of sites with higher risk of EtO exposure to Puerto Rico citizens. Steri-Tech, Balchem, and Mays were included in the original complaint and, as such, were put on notice of the claims against them. Pursuant to American Pipe, Danisha Ortiz-Santiago, Yamel Santiago-Rivera, Elba Meléndez-Figueroa, and Lianibel Colón-Sánchez’s claims are timely because the commencement of the class action on August 29, 2023, tolled the applicable statute of limitations “as to all asserted members of the class,” which includes them. American Pipe, 414 U.S. at 554.

Edward LifeSciences, Medtronic, and Customed sustain that the American Pipe doctrine is inapplicable to Iris Rivera-Vargas (asserting claims against Edwards LifeSciences, Balchem, and Mays), Idalia Vargas-Gratacós (asserting claims against Medtronic, Balchem, and Mays), and Juana Castro-Moreno (asserting claims against Customed, Balchem, and Mays), because none of the original plaintiffs in the original complaint asserted claims against them. Indeed, the original complaint did not have a single plaintiff allege to have suffered injury from EtO exposure by Edwards LifeSciences, Medtronic, or Customed. Plaintiffs in the original complaint lived in the

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vicinity of Steri-Tech’s facilities in Salinas. Although the allegations set forth by this subset of New Plaintiffs are the same as the ones asserted in the original complaint, Edwards LifeSciences, Medtronic, and Customed were not notified of the number and potential plaintiffs “who may participate in the judgment” because there were no plaintiffs that could have asserted actionable claims against them at that time. Crown, Cork & Seal Co., Inc., 462 U.S. at 353. Simply put, “if there is no case, there can be no tolling.” New Jersey Carpenters Health Fund v. DLJ Mortg. Capital, Inc., 2010 WL 6508190, at *2 (S.D.N.Y. Dec. 15, 2010) (finding that the American Pipe rule should not apply where the plaintiff that brought the dismissed claim was found by the court to have no standing). The original complaint was filed on August 29, 2023. Docket No. 1. Iris Rivera-Vargas, Idalia Vargas-Gratacós, and Juana Castro-Moreno were joined in February 2024. They allege, along with the rest of the Plaintiffs, to have found out of the causal link between their injuries and Sterilizer Defendants’ EtO emissions in 2022. Although the American Pipe doctrine is applied for the benefit of members of a class, the doctrine requires actionable claims to serve as an anchor for the claims of other class members. The American Pipe tolling doctrine is inapplicable to Iris Rivera-Vargas’ claims against Edwards LifeSciences, Idalia Vargas-Gratacós’ claims against Medtronic, and Juana Castro-Moreno’s claims against Customed. The same is true for their claims against Balchem and Mays. Although the original plaintiffs asserted claims against Balchem and Mays, those claims were for injuries caused by the EtO emissions of Steri-Tech in Salinas. Balchem and Mays were not made aware in the original complaint that they could be held liable for the EtO emissions of the Edwards LifeScience, Medtronic, and Customed facilities. Because Balchem and Mays were not put on notice of actionable claims other than those related to Salinas and were not made aware of the need to preserve evidence and witnesses in connection with the claims against Edwards LifeScience, Customed, and Medtronic, the American Pipe tolling doctrine is inapplicable to Iris Rivera-Vargas, Idalia Vargas-Gratacós, and Juana Castro-Moreno’s claims against Balchem and Mays.

Plaintiffs assert that, in any event, Iris Rivera-Vargas’ claims against Edwards LifeSciences, Balchem, and Mays, Idalia Vargas-Gratacós’ claims against Medtronic, Balchem, and Mays, and Juana Castro-Moreno’s claims against Customed, Balchem, and Mays survive under the continuous tort doctrine. Docket No. 83 at pp. 21-23. Under Puerto Rico law, the statute of limitation applicable to torts can be tolled if there is a continuing violation. Rivera Ruiz v. Mun.

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de Ponce, 196 P.R. Dec. 410, 417 (P.R. 2016).⁶ See also Miller v. Louthan, 2023 WL 11014926, at *3 (D.P.R. Nov. 15, 2023) (report and recommendation adopted in part, rejected in part, 2024 WL 1230255 (D.P.R. Mar. 22, 2024)). The Puerto Rico Supreme Court has defined a continuous tort as a “continued, or uninterrupted, disturbance of unlawful acts or omissions which cause foreseeable lasting damages.” McMillan v. Rodríguez-Negrón, 511 F. Supp. 3d 75, 83 (D.P.R. Dec. 18, 2020) (quoting Rivera Ruiz, 196 P.R. Dec. at 417). “Since the tortfeasor’s illegal acts are continuous, the cause of action continually renews itself, for the statute of limitation purposes, until the tortfeasor ceases his harmful conduct.” Id. A continuous tort, however, arises from ongoing unlawful conduct, not from a continuing harmful effect of the conduct. “For there to be a continuous tort, Defendants must be continuously acting, i.e., continuing to dump pollutants on Plaintiffs’ land.” M.R. (Vega Alta), Inc. v. Caribe Gen. Elec. Prods., Inc., 31 F. Supp. 2d 226, 240 (D.P.R. Dec. 3, 1998).

Plaintiffs allege that Defendants actions have been continuous: “This insidious chemical [...] is alarmingly prevalent in the air in many communities in Puerto Rico, where the toxin is continuously released from sterilization facilities[.]” (Docket No. 74 at p. 2); “Defendants never informed the residents of [Salinas, Añasco, Fajardo, and Villalba] or those who attend, live, pray or work nearby that they systematically emit EtO into the air, nor did Defendants warn them that these residents routinely and continuously breathe in [EtO];” (id. at ¶ 4); “[...] punish and deter each Defendant from repeating or continuing such unlawful conduct.” (id. at ¶ 116). Taken as true, these allegations establish that Defendants may have engaged in a continued pattern of unlawful acts or omissions. But not all plaintiffs are equally situated. Iris Rivera-Vargas stopped working within four (4) miles of Edward LifeSciences’ facilities in 2008. Docket No. 87 at p. 19. As such, Iris Rivera-Vargas’ injuries because of Defendants’ actions came to a halt when she stopped working in Añasco in 2008. Iris Rivera-Vargas had one year, from the moment she was put on notice of a possible connection between the EtO emissions (i.e., the 2022 announcement made by the EPA regarding EtO emissions) and her diagnosis, to assert a claim against Defendants. And nothing in the Amended Complaint at Docket No. 74 explains why the one-year statute of limitations should be tolled as to her. She was allegedly put on notice of who caused her injuries in 2022 but joined the action in 2024. Her claims against Edward LifeSciences, Balchem, and

⁶ A certified translation of this case was included in Civil No. 19-1639 (MDM) at Docket No. 94 and is incorporated to this Report and Recommendation as **Exhibit 1**.

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Mays are untimely. On other hand, Idalia Vargas-Gratacós and Juana Castro-Moreno continue to reside within four (4) miles of Medtronic's facility in Villalba and Customed's facility in Fajardo, respectively. Plaintiffs argue that Balchem and Mays continue to manufacture and distribute EtO, respectively, and that the EtO emissions from the Villalba and Fajardo facilities are ongoing. Idalia Vargas-Gratacós and Juana Castro-Moreno's claims against Medtronic and Customed, respectively, and Balchem and Mays survive dismissal under the continuous violation doctrine.

In sum, the claims of Jeanette Pérez-Maceira against Steri-Tech, Balchem, and Mays, Juan Luis Mateo-Pérez against Steri-Tech, Balchem, and Mays, and Lilliam Ortiz against Steri-Tech, Balchem, and Mays, are timely as they learned of the identity of the entity allegedly responsible for their injuries in 2022, within one year of the filing of this action. The claims of Danisha Ortiz-Santiago against Steri-Tech, Balchem, and Mays, Yamel Santiago-Rivera against Steri-Tech, Balchem, and Mays, Elba Meléndez-Figueroa against Steri-Tech, Balchem, and Mays, and Lianibel Colón-Sánchez against Steri-Tech, Balchem, and Mays survive by application of the American Pipe doctrine. Idalia Vargas-Gratacós and Juana Castro Moreno's claims against Medtronic and Customed, respectively, and Balchem and Mays survive under the continuous tort doctrine. Iris Rivera-Vargas' claims against Edward LifeSciences, Balchem, and Mays are untimely and should be dismissed.

3. Negligence (Count I)

Sterilizer Defendants argue that all of Plaintiffs' claims fail because Plaintiffs have not alleged a present injury and Puerto Rico law does not provide relief for potential, future injuries.⁷ Docket Nos. 76 at pp. 19-21, 79. Specifically, they argue that, although Plaintiffs allege that they have each been diagnosed with a medical condition, they have not alleged that those conditions were caused by exposure to EtO. Docket No. 76 at p. 21. And that absent an allegation that EtO

⁷ Plaintiffs seek a Defendant-funded medical monitoring program given the "high likelihood of latent disease developing decades from now" because of exposure to EtO emissions. Docket No. 74 at pp. 3, 17, 22. Despite not having pled the existence of any "subcellular changes," in their opposition to Defendants' motions to dismiss, Plaintiffs argue that they have suffered "subcellular changes that substantially increased the risk of serious disease and have suffered an economic injury in the form of the costs of medically necessary diagnostic testing any informed individual would reasonably undergo because of their now-increased risk of disease caused by their exposure to EO." Docket No. 83 at p. 38. Balchem and Mays do not weigh in. They will address class action certification and the relief for medical monitoring if the complaint survives this initial pleading stage. Docket No. 75 at p.1 n.1. Sterilizer Defendants urge the Court to dismiss Plaintiffs' request for relief in the form of medical monitoring damages because such a relief is not available under Puerto Rico law. Docket No. 76 at pp. 21-25. Because the class has not been certified and the relief for a medical monitoring program is contingent on that certification, dismissal of the relief for a medical monitoring program is premature.

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caused their conditions, Plaintiffs’ allegations of past diagnosis cannot satisfy the present-injury requirement in tort claims. Id. At the crux of Medtronic, Customed, Edward LifeSciences, and Steri-Tech’s argument is that many of Plaintiffs’ allegations contradict their position that they suffered a medical condition after being exposed to EtO. For instance, in the Amended Complaint, Plaintiffs aver that “[e]xposure to toxic chemicals **may cause** latent yet substantial injury, which should be compensated, **even if the full effect of the exposure is not immediately apparent;**” “[m]edical monitoring is necessary to detect the **potential onset of a serious illness or disease** due to physiological changes that indicate a substantial increase in **risk of harm** from exposure to EtO;” “preventing diagnostic tests for the **early detection of signs** or symptoms of latent cancers are medically necessary to assure early diagnosis and effective treatment, mitigating the **risk** of harm of these serious diseases[;]” [h]aving been harmed by regularly breathing in Defendants’ elevated levels of EtO, Plaintiffs ... seek as damages the costs of such diagnostic testing and medical monitoring, **in order to detect the early onset of disease[;]**” “the only source of EtO and **related cancer risk** largely comes from the [Sterilizer Defendants].” Docket No. 74 at ¶¶ 68, 70, 74, 76 (emphasis added). See also Docket No. 83 at p. 38 (Plaintiffs “have suffered subcellular changes that substantially increased the risk of serious disease and have suffered an economic injury in the form of the costs of medically necessary diagnostic testing and informed individual would reasonably undergo because of their **now-increased risk of disease** caused by their exposure to EtO.”) (emphasis added). Plaintiffs counter that they have been exposed to EtO which caused their injuries and damages. Docket No. 83 at pp. 32-33.

Plaintiffs’ negligence claim is governed by Puerto Rico’s general tort statute. Suero-Algarín v. CMT Hosp. Hima San Pablo Caguas, 957 F.3d 30, 39 (1st Cir. 2020). Article 1802 stated that “[a] person who by an act or omission causes damage to another through fault or negligence shall be obliged to repair the damage so done.” 31 P.R. Laws Ann. § 5141. To prevail in this claim, Plaintiffs must establish “(1) evidence of physical or emotional injury, (2) a negligent or intentional act or omission (the breach of duty element), and (3) a sufficient causal nexus between the injury and defendant’s act or omission (proximate cause).” González-Cabán v. JR Seafood Inc., 48 F.4th 10, 14 (1st Cir. 2022) (internal citations omitted). See also Díaz Ramos v. Hyundai Motor Co., 431 F.Supp.2d 209, 213 (D.P.R. May 19, 2006) (a cause of action for tort damages presupposes that plaintiff has suffered an actual injury caused by defendant’s negligence); Cintrón Alvarado v. Gómez, 147 D.P.R. 576, 589 (1999) (“In order for an injury to

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be redressed, the injury has to have truly been suffered and has to be proven.”) (cert. trans. at Docket No. 76-1). The breach of duty element is tied to a relevant duty of care, which is defined as “an obligation to anticipate and take measures against a danger that is reasonably foreseeable.” Id. (citing Baum-Holland v. Hilton El Con Mgmt., LLC, 964 F.3d 77, 88 (1st Cir. 2020)). A defendant’s duty of care may be established “(1) by statute or regulation; (2) ‘as the result of a special relationship between the parties that has arisen through custom; or (3) as the result of a traditionally recognized duty of care particular to the situation.” Baum-Holland, 964 F.3d at 88 (citing De Jesús-Adorno v. Browning Ferris Indus. of P.R., Inc., 160 F.3d 839, 842 (1st Cir. 1998)). To establish proximate cause, a plaintiff must prove by preponderance of the evidence that defendant’s breach of its duty of care caused the injury, and that the injury was reasonably foreseeable to the defendant. González-Cabán, 48 F.4th at 14-15; see also Cabán v. Centro Médico del Turabo, Inc., 2023 WL 5959189 at *9 (D.P.R. Sept. 13, 2023). Foreseeability is not established by the mere fact that an accident occurred. Id.

Plaintiffs do allege that, after exposure to EtO, they have each suffered specific health conditions. See Docket No. 74 at pp. 18-19 (Pérez-Maceira was diagnosed with breast cancer in 2016, Mateo-Pérez suffers asthma, Ortiz was diagnosed with thyroid cancer in 2022, Ortiz-Santiago was diagnosed with spina bifida in 1994, Santiago-Rivera was diagnosed with thyroid issues in 1976 and arthritis in 2021, Meléndez-Figueroa was diagnosed with maxillary sinus cancer in 2015, Colón-Sánchez was diagnosed with asthma in 2021, Rivera Vargas was diagnosed with uterine cancer in 2007, Vargas-Gratacós was diagnosed with melanoma, asthma, high blood pressure, and arthritis, and Castro-Moreno was diagnosed with stage 5 breast cancer in 2012). See also id. at ¶ 69 (“[Plaintiffs] suffered appreciable harm as a result of inhaling air poisoned with Defendants’ dangerously high EtO emissions.”), id. at ¶ 107 (“exposure makes it significantly more likely that Plaintiffs and class members will develop **further** injuries”) (emphasis added). They have thus plausibly alleged that those medical conditions were the consequence of exposure to EtO. Docket No. 74 at pp. 18-19. While Medtronic, Customed, and Steri-Tech are correct that, under Puerto Rico law, Plaintiffs are not entitled to compensation for potential or speculative injuries and that Plaintiffs would need to establish an actual injury to be entitled to relief, regardless of other expressions in the Amended Complaint, Plaintiffs have sufficiently alleged that they have suffered injuries because of EtO emissions from Sterilizer Defendants’ facilities and Article 1802

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could plausibly provide a basis for relief in favor of Plaintiffs to compensate for those injuries. Díaz-Ramos, 431 F.Supp.2d at 213.

Balchem and Mays request dismissal of the negligence claim as Plaintiffs cannot establish that Balchem and Mays owed them a duty and Plaintiffs have not alleged any connection between Balchem and Mays and the injuries caused by the emissions of EtO from Sterilizer Defendants' facilities. Docket Nos. 75 at pp. 9-10; 78 at p. 2. Specifically, Balchem argues that there is no plausible connection between Balchem and the emissions of EtO from Sterilizer Defendants' facilities, Plaintiffs failed to allege that Balchem breached a duty, and Plaintiffs cannot establish a proximate cause between Balchem's acts or omissions and the alleged emissions of EtO, much less to Plaintiffs' alleged injuries. Mays argues that is not connected in any way to the operation of the sterilizing facilities as its role has been to provide freight services to Balchem. Docket No. 78. Plaintiffs acknowledge that Balchem and Mays do not own or operate any EtO facilities in Puerto Rico. Docket No. 83 at p. 28. But counter that Balchem provides training to Sterilizer Defendants on the use and handling of EtO and that, although the Occupational Safety and Health Act of 1970 does not require Balchem to provide training, Balchem is an EPA technical registrant of EO. Id. at pp. 30-32. Plaintiffs rely on joint tortfeasor liability to pursue claims against all Defendants. Id. at pp. 28-30.

Plaintiffs have pled that Balchem provided training to Sterilizer Defendants on practices for handling EtO. See Docket No. 74 at ¶¶ 59, 65. As to Mays, Plaintiffs merely allege that Mays was the distributor of Balchem's EtO in Puerto Rico. See Docket No. 74 at ¶¶ 24, 25, 64, 66, 67. Liberally construed, Plaintiffs' allegations against Balchem and Mays in the Amended Complaint are the following: "[d]efendants chose to operate their businesses such that the supply chain culminates in the emission of EtO[;]" "[d]efendants – by way of failure to implement control measures to limit emissions, failure to upgrade sterilization equipment, ... and other unsafe practices – subjected Plaintiffs and the Puerto Rican communities to unhealthy and dangerous levels of EtO in order to increase profits and/or cut costs[;]" "[d]efendants failed to train their employees and managers, resulting in unsafe practices which created risky EtO sterilization practices with the goal of saving money." Docket No. 74 at ¶¶ 38, 44, 45. But none of these sufficiently plead a duty by Balchem or Mays. Plaintiffs acknowledge that the Occupational Safety and Health Act of 1970 does not require Balchem to provide training to Sterilizer Defendants. Docket No. 83 at p. 32. In fact, federal regulations on EtO impose the obligation to train employees

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on Sterilizer Defendants. See 29 C.F.R. § 1910.1047(j)(1)(iii) (2024) (“Employers shall ensure that each employee has access to labels on containers of EtO and to safety data sheets, and is trained in accordance with the requirements of HCS [Hazard Communication Standard] and paragraph (j)(3) of this section.”). And Plaintiffs’ threadbare argument that Balchem is an EPA technical registrant with “compliance responsibilities” is severely underdeveloped and waived. See Mega Media Holdings, Inc. v. Aerco Broadcasting Corp., 852 F.Supp.2d 189, 197 n.8 (D.P.R. Mar. 30, 2012) (quoting United States v. Zannino, 895 F.2d 1, 17 (1st Cir. 1990)). On the other hand, the sole allegation in the Amended Complaint as to Mays is that it distributed Balchem EtO to Sterilizer Defendants. See Docket No. 74 at ¶¶ 24, 25, 64, 66, 67. But there is no dispute that Mays’ relationship was strictly with Balchem and not with the Sterilizer Defendants. Plaintiffs have thus failed to identify a duty owed by Balchem or Mays that could give rise to a tort claim in their favor. The claim of negligence against Balchem and Mays should be dismissed.⁸

4. Gross Negligence (Count II)

Defendants move to dismiss Plaintiffs’ gross negligence claim because Puerto Rico law does not recognize a claim for gross negligence. Plaintiffs have not addressed Defendants’ request. Puerto Rico law does not recognize a discrete action for gross negligence. I recommend that Plaintiffs’ gross negligence claims be dismissed. See Rivera v. Kress Stores, P.R., Inc. (D.P.R. Oct. 13, 2023); Benito-Hernando v. Gavilanes, 849 F.Supp. 136, 140 (D.P.R. Apr. 6, 1994) (“[...] Puerto Rico courts do not recognize gross negligence or any other degrees of negligence found in common law.”).

5. Public and Private Nuisance Claims (Counts III and X)

Balchem and Mays challenge Plaintiffs’ nuisance claims.⁹ Puerto Rico law contemplates actions for private and public nuisance. P.R. Laws Ann. tit. 32 § 2761. Plaintiffs assert both and do not seek injunctive relief, solely damages. In their Amended Complaint, they allege that Defendants’ conduct of releasing EtO in the atmosphere has interfered with their right to public health and the enjoyment of life and property. Docket No. 74 at p. 29. Balchem and Mays seek dismissal of Plaintiffs’ nuisance claims because these are based on the alleged emissions of EtO

⁸ The surviving negligence claims would be: Jeanette Pérez-Maceira, José Mateo-Pérez, Lilliam Ortiz, Danisha Ortiz-Santiago, Yamel Santiago-Rivera, Elba Meléndez-Figueroa, and Lianibel Colón-Sánchez against Steri-Tech; Idalia Vargas Gratacós against Medtronic; Juana Castro Moreno against Customed.

⁹ Other than on statute of limitations grounds discussed above, the Sterilizer Defendants did not seek dismissal of the nuisance claims against them.

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and neither Balchem or Mays own or operate sterilizing facilities in Puerto Rico. Docket Nos. 75, 78. Plaintiffs again rest on Balchem's training of employees of Sterilizer Defendants, which in their view contributed to the mishandling of EtO. Docket No. 83 at p. 33. Plaintiffs do not address Mays' arguments.

A nuisance is defined as:

Anything which is injurious to health, indecent, or offensive to the senses, or an obstruction to free use of property so as to interfere with the comfortable enjoyment of life or property, or that is a nuisance to the wellbeing of a neighborhood, or to a large number of persons or that illegally obstructs free flow traffic in the usual manner by a lake, river, bay, stream channel or navigable basin or by a park, square, street, public road and other similar [] constitute a nuisance and the subject of an action.

P.R. Laws Ann. tit. 32, § 2761. Anything that represents an obstruction to the free use of property is a nuisance and may be the subject of an action brought by those whose property is injuriously affected or whose personal enjoyment is lessened by the nuisance. Torres v. Rodríguez, 101 D.P.R. 177, 1 P.R. Offic. Trans. 253, 258 (1973); Ortega Cabrera v. Tribunal Superior, 101 D.P.R. 612, 1 P.R. Offic. Trans. 842, 848 (1973). Article 277 was enacted "to provide a mechanism whereby an aggrieved party could obtain a judicial cease and desist order as to the nuisance, and subsequently be compensated for damages sustained during its duration." Marrero Hernández v. Esso Std. Oil de Puerto Rico, Inc., 2005 WL 1213664, at *3 (D.P.R. May 20, 2005). The cause of action has a dual purpose: the abatement of the nuisance and the compensation of damages caused by the nuisance. Ortega Cabrera, 1 P.R. Offic. Trans. at 848. "It is a question of safeguarding the property right, the security, and the health of the citizens." Id. Trial courts must observe whether the alleged nuisance (i.e., Sterilizer Defendants' EO emissions) "exceeds the bounds of reasonableness and, as a result the right which they also have to the comfortable enjoyment of life or property is destroyed or impaired, imposing a burden greater than they ought to be required to bear, thereby upsetting the equilibrium or balance necessary to harmonize the parties' correlative rights." Casiano v. Lozada-Torres, 91 D.P.R. 488, 499 (1964) at Docket No. 75-10 (cert. trans.). Reasonableness is determined on a case-by-case basis, but courts have considered the place where the activity occurs, the nature, extent, usefulness, and value of any such activity, the nature of the alleged damages, and the right or use affected by the alleged nuisance. SLG Flores Jiménez v. Colberg, 173 P.R. Dec. 843, 856 (2008) (cert. trans. at Docket No. 75-12).

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Plaintiffs defend against dismissal by arguing that Balchem’s “training [] to the employees of at least some of the Sterilizer Defendants partially contributed to the negligence use and handling of EtO, leading – in part – to the fugitive emissions that caused Plaintiffs’ injuries.” Docket No. 83 at p. 33. But the foregoing is insufficient to assert a nuisance claim. In a case of drilling and the consequent emission of odors and vapors, a Court in this District expressed that, under Puerto Rico law, plaintiffs need not show that the alleged nuisance has reached “poisonous levels,” a nuisance exists if the activity “provokes vomiting, dizziness or other physical discomforts.” Hernández v. Esso Std. Oil Co., 429 F.Supp.2d 469, 472-73 (D.P.R. May 2, 2006). Plaintiffs generally claim that Defendants’ conduct has interfered with the enjoyment of life and their properties. See Docket No. 74 at p. 28 (“By causing the emission of EtO into the atmosphere, Defendants have injuriously affected rights common to the general public, such as ... public health, public safety, public peace, public comfort, and public convenience.”). But the Amended Complaint is devoid of any specificity on how exactly the EtO emissions— which are not obvious to the senses as EtO is odorless and colorless— affected Plaintiffs’ property or welfare or how their personal enjoyment has been, or continues to be, lessened by the nuisance. SLG Flores Jiménez, 173 P.R. Dec. at 856. See Docket No. 74 at ¶¶ 31-32 (Plaintiffs allege that until the EPA announcement in 2022, they “were unaware that they were being subjected to dangerous levels of EtO, nor could [they] have known of the EtO emissions coming from the Defendants’ facilities.”). More importantly, there are no allegations that Balchem or Mays were operating the sterilizing facilities and causing the nuisance. See Municipalities of Bayamón v. Exxon Mobil Corp., 2025 WL 600430, at *42 (D.P.R. Feb. 20, 2025) (no allegations that defendants were burning fossil fuels themselves in Puerto Rico or operating facilities in Puerto Rico, no causal nexus between defendants’ acts or omissions and the damages claimed for any prior or ongoing conduct that can be said to be injurious to health and that interfered with the enjoyment of property; dismissal recommended). Indeed, because it is undisputed that Balchem and Mays do not operate the sterilizing facilities in Puerto Rico, they would be unable to abate the purported nuisance— the emission of EtO by the Sterilizer Defendants. See id. at 42 (cases “seem to suggest that the recovery of damages is dependent on abatement. In other words, that one goes with the other.”); Ortega Cabrera, 1 P.R. Offic. Trans. at 848 (cause of action has a dual purpose: the abatement of the nuisance and compensation for damages caused by the nuisance). To the extent that Plaintiffs have not pled that Balchem or Mays actually participate in the creation or continuation of the

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alleged nuisance or that they even have the ability to stop any such nuisance, Plaintiffs have failed to plead a casual nexus between their “acts or omissions and the damages claimed for any prior or ongoing conduct that can be said to be injurious to health and that interfered with the enjoyment of property by [Plaintiffs].” See Municipalities of Bayamón, 2025 WL 600430, at *42. I recommend that the nuisance causes of action against Balchem and Mays be dismissed.

6. Unjust Enrichment (Count XI)

Defendants seek dismissal of the cause of action for unjust enrichment because such a cause of action is subsidiary; a remedy for unjust enrichment is available only when there are no other forms of relief available. Defendants cite to Rivera Muñoz v. Horizon Lines Inc., 737 F.Supp.2d 57, 65 (D.P.R. 2010), P.R. Tel. Co. v. SprintCom, Inc., 662 F.3d 74, 97 (1st Cir. 2011), and Ocaso S.A., Compañía de Seguros y Reseguros v. P.R. Mar. Shipping Auth., 915 F.Supp. 1244, 1263 (D.P.R. 1996). Plaintiffs did not respond. Instead, they argued that the dismissal of this claim is premature at this stage of the proceedings. Docket No. 83 at p. 33. But to move to discovery and make Defendants incur in the costs of defending from such a cause of action, Plaintiffs must pass the plausibility test. Bell Atl. Corp. v. Twombly, 550 U.S. at 558. Plaintiffs have not as there are other forms of relief available in the instant case. See Ocaso, 915 F.Supp. at 1263 (quoting Medina & Medina v. Country Pride Foods Ltd., 631 F. Supp. 293, 302 (D.P.R. 1986), aff’d by 901 F.2d 181 (1st Cir. 1990)) (“claims for unjust enrichment are ‘subsidiary in nature and will only be available in situations where there is no available action to seek relief.’”). This will continue to be the case even after discovery.

Furthermore, to prove a claim for unjust enrichment, a plaintiff must establish: (1) the existence of enrichment; (2) a correlative loss; (3) nexus between loss and enrichment; (4) lack of cause for enrichment; and the (5) absence of a legal precept excluding application of enrichment without cause. Gov’t. of Puerto Rico v. Carpenter Co., 442 F.Supp.3d 464, 476 (D.P.R. Feb. 27, 2020); Puerto Rico Tel. Co. v. SprintCom, Inc., 662 F.3d 74, 97 (1st Cir. 2011). Even if the Court were to find that it is too early in the game to dismiss this claim on grounds that it is subsidiary to other claims, Plaintiffs have still not alleged the essential elements of the claim, particularly that there has been a “patrimonial shift, [] which [] cannot be rationally explained by the prevalent body of laws.” MCLP Asset Co., Inc. v. Stewart Title Guaranty Co., 731 F.Supp.3d 318, 343 (D.P.R. Apr. 24, 2025) (quoting Punta Lima, LLC v. Punta Lia Dev. Co., LLC, 440 F.Supp.3d

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130, 150 (D.P.R. Feb. 11, 2020)). Plaintiffs’ unjust enrichment claim would fail on this additional ground. I recommend that the unjust enrichment claim be dismissed as to all Defendants.

7. Product Liability

Although the 1930 Civil Code did not explicitly incorporate the doctrine of strict liability in products’ liability cases, Puerto Rico courts adopted the doctrine.¹⁰ Isla Nena Air Servs., Inc. v. Cessna Aircraft Co., 449 F.3d 85, 88 (1st Cir. 2006) (citing P.R. Laws Ann. tit. 31 § 5141); Guevara v. Dorsey Labs., Div. of Sandoz, Inc., 845 F.2d 364, 365 (1st Cir. 1988); Mendoza v. Cervecería Corona, 97 D.P.R. 499 (1969). Furthermore, Article 1542 of the 2020 Puerto Rico Civil Code codified the doctrine of strict liability for cases of defects in the design and manufacturing of a product. See P.R. Laws Ann. tit. 31 § 10807 (“Persons selling a product, in the flow of commerce, whose design or fabrication is unreasonably dangerous, are liable for the harm caused by said product regardless of whether or not there is tort of negligence by the same.”) (cert. trans. at Docket No. 76-8).

There are three types of product defects that trigger the application of the strict liability doctrine: (1) manufacturing defects; (2) design defects; and (3) defects for insufficiency of warnings or instructions. Álvarez-Cabrera v. Toyota Motor Sales, U.S.A., Inc., 2020 WL 3620204, at *3 (D.P.R. July 2, 2020); see also P.R. Laws Ann. tit. 31 § 10807. Generally, “[a] manufacturer is strictly liable in tort when an article he places on the market, [] proves to have a defect that causes injury to a human being.” Ayala v. Kia Motor Corp., 633 F.Supp.3d 555, 568 (D.P.R. Sept. 30, 2022) (quoting Rivera-Santana et al. v. Superior Pkg., Inc., 132 P.R. Dec. 115 (1992)). Plaintiff has the burden of proving that the product was defective, and that said defect was the cause of the injury. Pérez v. Hyundai Motor Co., 440 F. Supp. 2d 57, 72 (D.P.R. 2006). In other words, to establish strict liability, a plaintiff must prove that (1) the product had a defect that made the product unsafe, and (2) the defect proximately caused the alleged injury. Ayala, 633 F.Supp.3d at 569; Molinary-Fernández v. BMW of North America, LLC, 2021 WL 5263638, at *3 (D.P.R. Mar.

¹⁰ The 2020 Civil Code of Puerto Rico codified in articles 1541 to 1544 the existing rules on product liability. Articles 1541 to 1544 provide for strict liability to apply to all those involved in the distribution chain of defective products. Luis Muñoz-Arguelles, The 2020 Revision of the Puerto Rican Civil Code: A Brief Explanation of Major Changes, 15 Journal of Civil Law Students 393 (2023). See also White v. Sunnova Energy Corp., 2019 WL 1271471, at *3 (D.P.R. Mar. 15, 2019) (“In other words, all those who take part in the manufacturing and distribution chain of a product are solidary liable, along with the manufacturer, to the injured party.”). Plaintiffs set forth product liability claims that precede and postdate the 2020 Civil Code. Although product liability jurisprudence was codified in the 2020 Civil Code, the analysis remains the same.

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31, 2021). If the damages cannot be traced to a defect in the product, there can be no viable claim under the strict liability doctrine. Id.

a. Design Defects (Counts V, VIII, IX)

A plaintiff claiming damages for a design defect must prove the existence of a defect in the design and that said defect was the proximate cause of the injuries suffered. Ayala, 633 F.Supp.3d at 569. “To prove that the product was unreasonably dangerous, the evidence must show a relation of cause and effect.” Id. (cleaned up). Article 1544 of the 2020 Civil Code codifies the cause of action for defects in the design of a product. See P.R. Laws Ann. tit. 31 § 10809; Muñiz-Arguelles, The 2020 Revision of the Puerto Rican Civil Code: A Brief Explanation of Major Changes, at 424. There are two tests under which a claim for defects in product design can be established: the “consumer-expectations test” and the “risk-utility test.” Caraballo-Rodríguez v. Clark Equip. Co., 147 F. Supp. 2d 66, 71 (D.P.R. 2001); Vázquez-Filippetti v. Banco Popular de Puerto Rico, 504 F.3d 43, 52 (1st Cir. 2007). Under the consumer expectations test, a product is defective if it “failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.” Álvarez-Cabrera, 2020 WL 3620204, at *4 (quoting Betancourt Ruiz v. Toyota Motor Corp., 2007 WL 9760418, at *1 (D.P.R. 2007)). The risk-utility test requires a plaintiff to establish that defendant’s product’s design proximately caused its injuries. The burden of proof then shifts to the defendant to show that the “benefits of the design at issue outweigh the risk of danger inherent in such a design.” Álvarez-Cabrera, 2020 WL 3620204, at *4. “The risk-utility balancing test is designed to avoid converting the manufacturer into the insurer of every harm that arises out of a product from which the consumer derives utility.” Id. (cleaned up).

Defendants move to dismiss all claims premised on the defects of design of EtO. Sterilizer Defendants aver that all product liability claims must be dismissed as to them because they are mere users of EtO and do not sell or manufacture EtO. Docket No. 76 at pp. 34-36. Plaintiffs do not address the arguments of the Sterilizer Defendants. A design defect is “[a]n imperfection occurring when the seller or distributor could have reduced or avoided a foreseeable risk of harm by adopting a reasonable alternative design, and when, as a result of not using the alternative, the product or property is not reasonably safe.” García v. Hartford Financial Servs. Group, Inc., 2022 WL 2836272, at 1 (D.P.R. June 1, 2022) (quoting *Defect*, Black's Law Dictionary (11th ed. 2019)). Since Sterilizer Defendants are not in the business of manufacturing, distributing, or selling EtO, they could not have “adopted a reasonable alternative design” for EtO. Plaintiffs’ action for the

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defects in the design of EtO against the Sterilizer Defendants is not actionable. See P.R. Laws Ann. tit. 31 § 10807; Mestre v. Hilton Intern. of Puerto Rico, Inc., 156 F.3d 49, 54 (1st Cir. 1998) (quoting Restatement (Second) Torts § 402A) (courts have followed the principles of product liability contained in the Restatement (Second) Torts § 402A which limit the application of product liability to manufacturers and sellers of products. That is, “Section 402A applies, however, only if ‘the seller is engaged in the business of selling such a product.’”).

Balchem and Mays claim that Plaintiffs alleged neither a defect in EtO nor causation. Plaintiffs allege that “Defendants’ EtO mixtures and EtO-containing products [...] constitute an unreasonably and inherently dangerous design [...] in that they contained EtO, a known toxic substance and carcinogen[.]” Docket No. 74 at ¶ 147. And that the “products’ toxicity, ability to bioaccumulate, inability to be contained, and environmental persistence rendered [EtO] defective and unreasonably dangerous at all times.” Id. at ¶ 148. But as Plaintiffs acknowledge in their opposition, the product at issue is 100% EtO. Docket No. 83 at p. 34. And for a claim based on defective design to be actionable the challenge cannot be to the product itself; it must be to a defect in its design. Ayala, 633 F. Supp. 3d at 569-70, 73-74; City of Philadelphia v. Lead Indus. Ass’n, 1992 WL 98482, at *3 (E.D. Pa. Apr. 23, 1992). Plaintiffs rely on bald allegations to assert a claim for the purportedly defective design of EtO. Dismissal of those claims against Balchem and Mays is warranted. See id. at 569 (quoting Mendoza v. Cervecería Corona, 97 P.R. Dec. 499, 512 (1969) (“In sum, ‘[i]f the damage is not attributable to a defect of the product, there is no ground for applying the strict liability rule.’”)).

Furthermore, Plaintiffs have not sufficiently pled a defective design of EtO under the consumer expectation or risk-utility tests. First, the consumer expectation test “cannot be the basis of liability in cases involving complex technical matters.” Álvarez-Cabrera, 2020 WL 3620204, at *4. The consumer-expectation test is “reserved for cases in which the everyday experience of the product’s users permits a conclusion that the product’s design violated minimum safety assumptions, and is thus defective regardless of expert opinion about the merits of the design.” Collazo-Santiago v. Toyota Motor Corp., 937 F.Supp. 134, 139 (D.P.R. 1996). Plaintiffs have not alleged what is the ordinary consumer’s expectation in using the product as intended. Id. Second, Plaintiffs allege that “the risk of danger inherent in the design of the Defendants’ ETO mixtures and ETO-containing products drastically outweighed any perceived benefits of the design[.]” Docket No. 74 at ¶ 150. But have not pled that EtO emissions proximately caused a design defect

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injury. Ayala, 633 F.Supp.3d at 569. Plaintiffs’ pleadings are thus also insufficient to establish design defect liability based on the risk-utility test. Plaintiffs’ claims for the defective design of EtO against Balchem and Mays should be dismissed.

b. Failure to Warn (Counts IV, VI, VII)¹¹

Plaintiffs contend that Defendants’ EtO lacked adequate warnings or instructions concerning the dangers and hazards associated with EtO. Docket No. 74 at pp. 29, 32, 34. And that Defendants “manufactured, distributed, marketed, promoted, and sold EtO and EtO-containing products, [and] they knew their products were not safe and were likely[,] if not certain[,] to cause toxic EtO contamination of lands[.]” Id. at p. 29. Balchem moves to dismiss because Plaintiffs admit in their Amended Complaint that the end users of EtO—the Sterilizer Defendants—knew or should have known of the potential dangers associated with EtO. Docket No. 75 at p. 26. And that the warnings and instructions provided by Balchem in the label attached to the product, as well as a Safety Data Sheet (“SDS”), could not have changed Sterilizer Defendants’ conduct. Moreover, Balchem argues that it could not have warned about EtO emissions from facilities that are not subject to its control. Mays joined Balchem’s arguments and adds that Plaintiffs have not alleged inadequate warning by Mays. Docket No. 78 at p. 3. Plaintiffs counter that employees of Sterilizer Defendants lacked proper training on the use of EtO and that, if the Sterilizer Defendants had been properly warned, “they would not have engaged in the negligent conduct alleged in the complaint.” Docket No. 83 at pp. 45-46. They also posit that the EtO warnings were inadequate because they failed to warn Sterilizer Defendants about the impact to nearby communities. Plaintiffs do not address Mays’ argument.

To prove a failure to warn cause of action under Puerto Rico law, Plaintiffs must show that: “(1) the manufacturer knew or should have known of the risk inherent in the product; (2) there were no warnings or instructions, or those provided were inadequate; (3) the absence of warnings made the product inherently dangerous; and (4) the absence of adequate warnings or instructions was the proximate cause of plaintiff’s injury.” Cruz Vargas v. R.J. Reynolds Tobacco Co., 348 F.3d 271, 276 (1st Cir. 2003) (quoting Aponte Rivera v. Sears Roebuck, 144 D.P.R. 830 (1998)). Plaintiffs’ failure to warn claims does not hold water because the Amended Complaint is devoid

¹¹ Plaintiffs style Count IV as a claim for defective design. However, that claim alleges Defendants’ failure to provide instructions or warnings. See Docket No. 74 at pp. 28-29.

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of allegations as to the fourth prong of the failure to warn test. Plaintiffs do not allege that the EtO purportedly manufactured by Balchem lacked warnings or instructions. Instead, they allege that the instructions were inadequate because Balchem failed to warn Sterilizer Defendants about the impact to nearby communities. Docket No. 83 at pp. 45-46. But Plaintiffs admit that Sterilizer Defendants were aware of EtO's effects, regardless of whether Balchem warned them or not. Docket No. 74 at ¶ 6. And Plaintiffs fail to sufficiently allege how any purported defect in the warnings caused their injuries. See Silva v. American Airlines, Inc., 960 F.Supp. 528, 533 (D.P.R. Apr. 16, 1997); SUEZ Water New York Inc. v. E.I. du Pont de Nemours and Co., 578 F.Supp.3d 511, 563 (S.D.N.Y. Jan. 4, 2022) (dismissing failure to warn claim because plaintiff did not allege any facts regarding what warnings should have been given). Plaintiffs limit themselves to claim, in a conclusory manner, that Balchem "failed to provide adequate warnings and/or instructions." Docket No. 74 at ¶ 135. There is no allegation as to how the warning or instructions or the trainings provided by Balchem would have ameliorated their harm. See Rodríguez v. Torres, 2015 WL 1138256, at *10-11 (D.P.R. Mar. 13, 2015) ("[i]nadequate warnings cannot serve as a proximate cause of injuries where adequate warnings about have resulted in the same injuries") (quoting Barry A. Lindahl, 3 Modern Tort Law: Liability and Litigation § 24:43 (2d ed.)). "Nor do[] Plaintiff[s] allege how, if the warnings were given, the industrial manufacturers or the end-users would have responded or how the harm to Plaintiff[s] would have been averted. SUEZ Water New York Inc., 578 F.Supp.3d at 563. Because Plaintiffs do not allege facts from which it can be reasonably inferred that Balchem failed to provide adequate warnings or instructions for the EtO or that the failure to warn was a proximate cause of their harm, their failure-to-warn claim against Balchem must be dismissed. García, 2022 WL 2836272, at *2. The failure to warn claims fail as to Mays for the same reasons.

III. Conclusion

For the reasons discussed above, the undersigned recommends that the Motions to Dismiss at Docket Nos. 76 and 79 be **GRANTED in part and DENIED in part**, and the Motions to Dismiss at Docket Nos. 75 and 78 be **GRANTED**. In sum, the undersigned recommends the dismissal of the following: Iris Rivera-Vargas' claims against Edward LifeSciences, Balchem, and Mays, all negligence claims against Balchem and Mays, private and public nuisance claims against Balchem and Mays, and all gross negligence, unjust-enrichment, design defects, and failure to warn claims. The negligence claims of (1) Jeanette Pérez-Maceira, José Mateo-Pérez, Lilliam

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Ortiz, Danisha Ortiz-Santiago, Yamel Santiago-Rivera, Elba Meléndez-Figueroa, and Lianibel Colón-Sánchez against Steri-Tech, (2) Idalia Vargas Gratacós against Medtronic, and (3) Juana Castro Moreno against Customed, and the private and public nuisance claims against Steri-Tech, Medtronic and Customed would remain.

This Report and Recommendation is filed pursuant to 28 U.S.C. §636(b)(1) and Rule 72(d) of the Local Rules of this District Court. Pursuant to Local Rule 72(d), the parties have **fourteen (14) days** to file any objections to this Report and Recommendation. Failure to file specific objections within the specified time precludes further review. See Thomas v. Arn, 474 U.S. 140, 155 (1985); Davet v. Maccarone, 973 F. 2d 22, 30-31 (1st Cir. 1992); Maisonet v. Genett Group, Inc., 863 F.Supp.2d 138, 143 (D.P.R. 2012) (absent specific objection, no obligation to review portion of Magistrate Judge’s recommendation).

IT IS SO RECOMMENDED.

In San Juan, Puerto Rico, this 23rd day of May 2025.

s/Giselle López-Soler
GISELLE LÓPEZ-SOLER
United States Magistrate Judge